



## Information Sheet 3

### ***Dioxin Reassessment Process: EPA is Moving Toward Completion of the Dioxin Reassessment***

The U.S. Environmental Protection Agency's (EPA) is in the process of completing its reassessment of dioxin exposure and human health effects entitled, "*Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.*" The Agency expects that the completed reassessment will be available before the end of the year. The purpose of this *information sheet* is to describe briefly the process that EPA has used in developing the final reassessment and to apprise the public about the remaining steps needed to bring this complex scientific activity to a close.

**BACKGROUND:** In April 1991, EPA announced that it would conduct a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA began this task in light of significant advances in our scientific understanding of mechanisms of dioxin toxicity, significant new studies of dioxin's carcinogenic potential in humans and increased evidence of other adverse health effects. EPA has worked to make each phase of the dioxin reassessment an open and participatory process. These efforts have included the involvement of outside scientists as principal authors of several chapters, frequent public meetings to report progress and take public comment, and publication of early drafts for public comment and peer review. Early in the reassessment process, EPA held public meetings (1991 and 1992) to inform the public of the Agency's plans and activities for the reassessment, to hear and receive public comments and reviews of the proposed plans, and to receive any current, scientifically relevant information. In 1992 and 1993, the Agency convened three peer-review workshops to review early drafts of the reassessment chapters. The Agency remains committed to an open and participatory process as it approaches the final reassessment.

#### **1994 PUBLIC REVIEW DRAFT AND 1995 SCIENCE ADVISORY BOARD (SAB) REVIEW:**

In September 1994, EPA released the external review drafts of the health effects and exposure documents which amounted to over 2,200 pages. EPA took public comment on the drafts, followed by SAB review of the draft dioxin reassessment in May 1995. The SAB's report was received in Fall of that year. In its report to the Agency, the SAB responded favorably to most of the reassessment, but recommended revision of two key sections. The SAB recommended that Chapter 8: Dose-Response Modeling for TCDD and the Risk Characterization document, be revised. Further, it recommended development of an additional document that would focus on the toxicity equivalent factors (TEFs) for dioxin and dioxin-like compounds. In addition to these substantive recommendations, the SAB suggested that the redrafting process include broader participation of outside scientists from both public and private sectors. They also requested that the two redrafted chapters and the new TEF chapter be submitted to independent external peer review, before being returned to the SAB for re-review. With respect to Chapters 1-7 of the health document and the full exposure reassessment document, the SAB accepted these sections. It suggested that they be updated to address public and SAB comments and to incorporate new scientific data, but stated that further review of these sections by that SAB was not needed.

**POST-SAB REVISION PROCESS:** After receipt of the SAB's report, the Agency worked with over 40 stakeholders from the private and public sectors, representing environmental, industry, academic, state, and other public interest and public health communities, on next steps and to gather input on possible approaches for conducting the revision process. The Agency has tried to keep these individuals apprised of reassessment activities at critical points in the revision process. The Agency expects that these individuals will be important avenues of public input as the revised dioxin reassessment sections are made available for public comment. The three sections that will undergo further review by the SAB are:

**Chapter 8: Dose-Response Modeling →** This chapter was revised using a writing team process. The writing team was composed of a dozen leading scientific experts in fields related to dioxin health effects and quantitative risk assessment. These experts came from a wide range of public and private organizations, as well as academia. The draft Chapter 8 underwent public comment and external peer review in March 1997. A writing team developed the draft final chapter based on the peer review and public comments and any relevant new scientific data, in January 2000. This draft final chapter will then undergo re-review by the SAB.

**TEF chapter →** This new document, now identified as Chapter 9, was developed as a result of a recommendation from the SAB to gather in one place the discussion and scientific information on the complex issue and use of TEFs for dioxin and dioxin-like compounds. The draft TEF chapter, which was developed by a team of experts, is completed. An external peer review workshop is planned, followed by an SAB review.

**Integrated Summary and Risk Characterization →** This section, formerly identified as Chapter 9, also followed the writing team process. A preliminary revised draft was developed by a writing group made up of scientists from a wide range of public and private organizations, as well as academia, and was reviewed by the stakeholders. This preliminary draft was used as the framework for an extensively revised document developed by a small internal EPA writing group. An external peer review workshop is planned, followed by re-review by the SAB.

**STRUCTURE OF FINAL REASSESSMENT DOCUMENT:** The final dioxin reassessment will consist of three parts. *Part I: Estimating Exposure to Dioxin-Like Compounds* will include four volumes that focus on sources, levels of dioxin-like compounds in environmental media, and human exposures. *Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will consist of two volumes that include information on critical human health end points, mode of action, pharmacokinetics, dose-response, and TEFs. Part II will have nine chapters. *Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will be a stand alone document. In this part, key findings pertinent to understanding the potential hazards and risks of dioxins are described and integrated, including a discussion of all important assumptions and uncertainties.

**NEXT STEPS:** The following major steps are being planned for review of EPA's dioxin reassessment:

**June 2000 → Redrafted Documents Submitted for Peer Review:** In June, the revised Chapter 9 and the Integrated Summary and Risk Characterization resulting from the internal EPA review and comment, as well as review by other federal agencies, will be submitted for independent scientific peer review. A peer review meeting is scheduled for July 25 and 26 in Washington, DC. The Peer Review drafts will be available on the Internet (down-loadable PDF file) and in a limited number of paper

copies. Background documents will also be available on the Internet and on Compact Disk-Read Only Memory (CD-ROM). The background information consists primarily of Part I: Estimating Exposure to Dioxin-Like Compounds (Volumes 2-4) and Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds (Chapters 1-8). The background documents will be available on CD-ROM and via the Internet only.

**Federal Register (FR) Notice published:** An *FR* notice will give public notice of the upcoming external peer review meeting and announce the availability of the draft documents and the beginning of a public comment period. This will be a “rolling public comment period.” The Agency will continue to take public comments up to and shortly after the SAB review meeting scheduled for later in the year. This means one continuous comment period will be used to cover both the peer review drafts and the later drafts to be submitted to the SAB. As background information only, the draft final *Part I: Estimating Exposure to Dioxin-Like Compounds* and *Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* (Chapters 1-7 and SAB Review Draft of Chapter 8 ) will be available both on the Internet and as part of the CD ROM package. The Agency will not be taking additional public comment on Part I or Chapters 1-7 of Part II. These sections have been accepted by the SAB. As Chapter 8 will be going back to the SAB for review, public comments will be requested at that time.

**July 2000 → External Peer Review:** An External Peer Review will take place in the Washington, DC area on July 25 and 26. The Agency is using a private contractor to plan and conduct the meeting and to identify and secure the services of independent expert scientists as peer reviewers. This peer review meeting will be for the purpose of reviewing the draft *Part II: Chapter 9: Toxicity Equivalence Factors (TEF) for Dioxin and Related Compounds* and draft *Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds*. The public will be invited to attend the peer review meeting as observers. A limited amount of time will be made available for comments by the observers.

**September 2000 → Revised Drafts Sent to SAB for Final Review:** Based upon comments received from the peer review panel and the rolling public comment period, the TEF chapter and the Integrated Summary and Risk Characterization, will be revised, as appropriate, and formally submitted to the SAB. Also submitted to the SAB for review will be the revised Dose-Response Modeling chapter.

**October/November 2000 → SAB Review Meeting:** The SAB meeting to review these three sections of the dioxin reassessment is being planned for October. Final SAB approval is needed to produce a final EPA dioxin reassessment document for public release.

It is important to note that the dates identified for each step are dependent on public participation at each of the review phases; the nature of the comments received may result in unexpected delays. However, it is EPA's intent to complete its reassessment of this important environmental health issue before the end of the year.

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